Citation:

Utsugi MT, Ohkubo T, Kikuya M, Kurimoto A, Sato RI, Suzuki K, Metoki H, Hara A, Tsubono Y, Imai Y. Fruit and vegetable consumption and the risk of hypertension determined by self measurement of blood pressure at home: the Ohasama study. *Hypertens Res.* 2008 Jul;31(7):1435-43.

PubMed ID: 18957815

Study Design:

Cross-sectional Analysis of Longitudinal Study

Class:

D - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To investigate the association of fruit and vegetable consumption with the risk of hypertension diagnosed by home blood pressure.

Inclusion Criteria:

- Residents of Ohasama, Japan
- Aged 35 and over
- Completed home blood pressure measurements

Exclusion Criteria:

- Hospitalized, mentally ill or bedridden (n = 213)
- Subjects who worked outside the town (n = 1,410)
- <3 measurements of home blood pressure (n = 114)
- Incomplete questionnaire (n = 167)
- Extreme levels of energy intake (n = 81)

Description of Study Protocol:

Recruitment

The present study is part of the Ohasama study, a longitudinal community-based observational study of individuals who have participated in the study of home blood pressure measurement project in Ohasama, Iwate Prefecture, Japan.

Design: Cross-sectional Analysis of Longitudinal Study

Blinding used (if applicable): not applicable

Intervention (if applicable): not applicable

Statistical Analysis

- Subjects were divided into tertiles according to fruit, vegetable, potassium, vitamin C and beta-carotene consumption
- Differences between social and lifestyle characteristics of each fruit and vegetable intake were tested for statistical significance with Student's t test, ANOVA for continuous variables or chi-square test for categorical variables
- To examine how the consumption of fruits and vegetables or other related nutrients was associated with a risk of hypertension, multiple logistic regression analysis was conducted

Data Collection Summary:

Timing of Measurements

One time measurement.

Dependent Variables

- Risk of hypertension diagnosed by home blood pressure
- Hypertension was defined as home systolic/diastolic blood pressure > 135/85 mmHg and/or the use of antihypertensive medication

Independent Variables

- Fruit and vegetable consumption
- Dietary intake measured using a 141-item food frequency questionnaire

Control Variables

- Sex
- Age
- Smoking
- Alcohol consumption
- Exercise
- Height, weight, BMI
- Energy-adjusted fat intake
- Sodium consumption
- Past history of diabetes and hypercholesterolemia

Description of Actual Data Sample:

Initial N: 1,931 residents consented to participate.

Attrition (final N): After application of exclusion criteria, 1,569 residents were analyzed (642 men and 927 women).

Age: mean 60.0 ± 12.8 years

Ethnicity: assumed Japanese

Other relevant demographics:

Anthropometrics

Those who completely fulfilled study criteria were characterized by a significantly higher proportion of current smokers, a lower amount of total energy intake, a higher BMI, and also differed in age, fat and sodium intakes.

Location: Ohasama, Japan

Summary of Results:

Key Findings:

- The prevalence of home hypertension was 39.4% for men and 29.3% for women
- After adjustment for all potential confounding factors, the highest-tertile consumptions of fruits, vegetables, potassium and vitamin C were associated with a significantly lower risk of hypertension (45%, 38%, 46%, and 43% lower risk of home hypertension, respectively).

Odds Ratios (95% Confidence Intervals) for the Association Between Fruit and Vegetable Consumption and the Risk of Home Hypertension (n = 1,569)

Variables	Adjusted Odds Ratio	P value
Fruit - Highest (n = 523)	0.55 (0.37 - 0.81)	0.002
Fruit - Medium (n=523)	0.82 (0.57 - 1.18)	0.291
P for Trend	0.009	
Vegetable - Highest $(n = 523)$	0.62 (0.40 - 0.95)	0.029
Vegetable - Medium (n = 523)	0.57 (0.39 - 0.84)	0.005
P for Trend	0.012	
Potassium - Highest $(n = 523)$	0.54 (0.32 - 0.88)	0.015
Potassium - Medium (n = 522)	0.48 (0.31 - 0.73)	0.001
P for Trend	0.003	
Vitamin C - Highest $(n = 522)$	0.57 (0.37 - 0.87)	0.010
Vitamin C - Medium (n = 524)	0.70 (0.48 - 1.02)	0.064
P for Trend	0.030	
Beta- carotene - Highest (n = 522)	0.67 (0.42 - 1.06)	0.087

Beta-carotene - 0.69 (0.46 - 1.03) 0.067

Medium (n = 523)

P for Trend 0.136

Adjusted for age, gender, BMI, frequency of exercise, smoking status, alcohol consumption, fat intake, sodium consumption, and past history of diabetes and hypercholesterolemia.

Other Findings

- Mean consumptions of fruits and vegetables were 108 and 63 g/day, respectively
- Mean home blood systolic/diastolic blood pressures were 122/75 mmHg
- Compared with those in the lowest tertile of fruit consumption, those in the highest tertile were more likely to be women, never or ex-smokers, and older; they were also more likely to have higher BMI annd lower amounts of alcohol consumption
- Similar tendencies were observed for vegetable consumption

Author Conclusion:

The present results from the Ohasama study suggest that high-level consumption of fruits, vegetables and other related micronutrients present mainly in fruits and vegetables are potentially associated with a lower risk of hypertension. While the mechanism for blood pressure-lowering via fruit and vegetable consumption is not yet clear, selective consumption of healthy foods and nutrients may lead to prevention and treatment of hypertension.

Reviewer Comments:

Those who completely fulfilled study criteria were characterized by a significantly higher proportion of current smokers, a lower amount of total energy intake, a higher BMI, and also differed in age, fat and sodium intakes. Authors note the following limitations:

- We could not determine whether additional sodium was consumed in the form of table salt or salt added during cooking, and we did not monitor the consumption of pre-packaged, convenience or fast foods, or the frequency of high-sodium restaurant foods; therefore, the true sodium intake might be underestimated
- Information on food and nutrient composition in the present study were obtained on the basis of a dietary recall
- Possibility of selection bias needs to be considered nonparticipants were older, had higher blood pressure levels, and higher energy intake in comparison to those who participated in the study

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)



	2. Did the authors study an outcome (dependent variable) or			
		the patients/clients/population group would care about?		
	3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes	
	4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes	
Valid	ity Questions			
1.	Was the research question clearly stated?			
	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes	
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes	
	1.3.	Were the target population and setting specified?	Yes	
2.	Was the sele	ction of study subjects/patients free from bias?	???	
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes	
	2.2.	Were criteria applied equally to all study groups?	N/A	
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes	
	2.4.	Were the subjects/patients a representative sample of the relevant population?	???	
3.	Were study	groups comparable?	N/A	
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A	
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A	
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes	
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A	

	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method	of handling withdrawals described?	Yes
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	N/A
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	Yes
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	Yes
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		ention/therapeutic regimens/exposure factor or procedure and ison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	N/A

	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	N/A
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcor	nes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	N/A
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	???
	7.7.	Were the measurements conducted consistently across groups?	N/A
8.	Was the stat outcome ind	istical analysis appropriate for the study design and type of icators?	Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	Are conclusi consideratio	ons supported by results with biases and limitations taken into n?	Yes
	9.1.	Is there a discussion of findings?	Yes

	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	Is bias due t	o study's funding or sponsorship unlikely?	Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes

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